

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 14

REMARKS

This amendment is responsive to the Office Action mailed December 28, 2004 (hereinafter referred to as "the instant Action"). Original claims 1-46 and new claims 47 and 48 submitted with Applicant's amendment on September 30, 2004 are under examination in the present action. All pending claims stand rejected.

1. Applicant submits concurrently with this reply a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 together with the fee set forth in 37 C.F.R. § 1.17(e). Applicant states that said Request is timely due to the finality of the instant Action and that the present application is eligible for continued examination under 37 C.F.R. § 1.114. Applicant respectfully requests withdrawal of the finality of the instant Action and entry of the above amended claims set.

2. Claims 1 - 48 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In support of this rejection the Examiner states that "[t]he specification does not recite 'intermediate subsurface' recited [sic] in line 4 of claim 1." Applicant respectfully states that claim 1 has no such requirement and that line 4 of claim 1 refers to an **immediate** subsurface not an intermediate subsurface as opined by the Examiner. Since this rejection is clearly erroneous, it must be withdrawn.

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 15

Applicant respectfully requests withdrawal of the rejection of claims 1 - 48 under 35 U.S.C. §112, first paragraph.

3. Claims 1 - 48 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner is of the opinion that the term "immediate," as used in line 4 of claim 1, is "relative and subjective, and dependent on individual interpretation [sic]." Without conceding the appropriateness of the Examiner's opinion and in an effort solely to advance the prosecution of the subject application to grant, Applicant amends claim 1 to delete the offending term. Support for the term "subsurface" is found in the specification on page 14, lines 6 to 7.

Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 1 - 48 under 35 U.S.C. §112, first paragraph.

4. Claims 1 - 11, 22, 23, 26 - 33 and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,672,659 issued to Shalaby *et al.* (hereinafter referred to as "the '659 patent") or international Patent Publication WO 97/39738 in the names of Ignatious *et al.* (hereinafter referred to as "the '738 publication") in view of U.S. Patent 5,612,052 issued to Shalaby *et al.* (hereinafter referred to as "the '052 patent") and U.S. Patent 5,366,756 issued to Chesterfield *et al.*

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 16

(hereinafter referred to as "the '756 patent"). In support thereof, the Examiner reasons

[i]t would have been obvious to form the polymer of [the '659 patent] or [the '738 publication] into a microparticle prior to conjugating with the polypeptide or protein as suggested by [the '052 patent] and [the '756 patent] forming a polymer microparticle and immobilizing a drug and/or growth promoter on the microparticle. Forming the microparticle before binding the protein or polypeptide would have expected to provide the protein or polypeptide on the surface of the microparticle and make it more readily available. When coating the microparticle as suggested by [the '052 patent] and [the '756 patent], the polypeptide will inherently be on the surface and immediate subsurface of the microparticle. The conditions of dependent claims would have been matters of obvious choice in view of conditions disclosed by the references.

Applicant respectfully submits that the Examiner continues to misapply the correct rule of law with respect to a rejection under 35 U.S.C. §103(a).

In an effort to preserve the record, Applicant incorporates by reference the argument directed to the relevance of the cited references detailed in his reply submitted September 30, 2004 as if recited in its entirety herein.

Applicant respectfully submits that the Examiner has not met his initial burden to establish a *prima facie* case of obviousness as mandated by *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 17

Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1990). See MPEP §§2143 - 2143.03.

With respect to the first criteria, the Examiner has failed to provide some suggestion of the desirability of doing what the Inventor of this application has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or implicitly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP §§2144 - 2144.9. The Examiner fails to identify an expressed or implicit suggestion in any of the four references to combine the teachings as detailed in the instant Action. "When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper." *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & App. & Inter. 1986). See MPEP §2142. The Examiner does not do so relying on his own hindsight

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 18

and speculation that the combination would in fact result in the claimed invention.

As for the 2nd prong of the requirement of *In re Vaeck*, absent some suggestion in the art that the combination of the four references cited by the Examiner would be successful, the Examiner's opinion that such a combination would be successful is merely speculative and inappropriate when making a rejection under 35 U.S.C. §103(a). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. See M.P.E.P., citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The Examiner's unsupported position that the discussed combination would have been obvious, can only be based on the Examiner's review of the present application. It is well-settled law that it is improper to use Applicant's disclosure to support an obvious rejection. *In re Carroll*, 202 U.S.P.Q. 571 (C.C.P.A. 1979); *In re Ruff*, 256 F.2d 590, 118 U.S.P.Q. 340 (C.C.P.A. 1958).

With respect to the 3rd prong of the requirements of *In re Vaeck*, requiring that the prior art references, when combined, must teach or suggest all of the claim limitations, in an effort to better distinguish the present invention over the cited prior art references, Applicant has amended claim 1 to require that the polymer core be substantially free of any peptide, protein or combination thereof. As noted by the Examiner the primary documents, i.e., the '659 patent and the '738 reference, are both

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 19

directed to conjugates formed "by combining a solution of the polymer with a solution of the polypeptide" which would result in a microparticle comprised of homogenous mixture of both the polymer and bioactive agent. Claim 1 is amended to require that the claimed microparticles be comprised of a mostly homogenous polymer core with a bioactive agent dispersed thereon. Applicant respectfully submits that none of the prior art references cited by the Examiner have such a requirement. "To establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). See MPEP §2143.03. Applicant respectfully asserts that the 3rd requirement for a rejection under 35 U.S.C. §103(a), as set forth in *In re Vaeck*, has not been met, and as such, said rejection is improper.

Applicant respectfully requests the reconsideration of the rejection of claims 1 - 11, 22, 23, 26 - 33 and 47 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,672,659 issued to Shalaby et al. or international Patent Publication WO 97/39738 in the names of Ignatious et al. in further view of U.S. Patent 5,612,052 issued to Shalaby et al. and U.S. Patent 5,366,756 issued to Chesterfield et al. Applicant contends that based on the above-argument that said rejection is erroneous

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 20

and/or has been overcome by amendment. Applicant respectfully requests the withdrawal of said rejection.

5. Claims 12 - 21, 24, 25, 34 - 46 and 48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,672,659 issued to Shalaby *et al.* (hereinafter referred to as "the '659 patent") or international Patent Publication WO 97/39738 in the names of Ignatious *et al.* (hereinafter referred to as "the '738 publication") in view of U.S. Patent 5,612,052 issued to Shalaby *et al.* (hereinafter referred to as "the '052 patent") and U.S. Patent 5,366,756 issued to Chesterfield *et al.* (hereinafter referred to as "the '756 patent") and in further view of international Patent Publication WO 92/11844 in the names of Auer *et al.* and U.S. Patent 5,795,922 issued to Demian *et al.* for the reasons set forth previously. Without addressing the merits of the Examiner's reasoning for the recited rejection, Applicant asserts that since claim 1, upon which claims 12 - 21, 24, 25, 34 - 46 and 48 are dependent thereon, is nonobvious over the '659 patent or the '738 publication in further view of the '052 patent and the '756 patent, claims 12 - 21, 24, 25, 34 - 46 and 48 are also nonobvious over these references either alone or in combination. It is a well established tenet of U.S. patent law that a dependent claim is not rendered obvious by art that does not render obvious the base claim. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Neither the Auer nor Demian references were cited against the base claim and as such

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 21

can not render the dependent claims obvious under the holding of *In re Fine*.

Applicant respectfully requests the reconsideration of the rejection of claims 12 - 21, 24, 25, 34 - 46 and 48 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,672,659 issued to Shalaby *et al.* or international Patent Publication WO 97/39738 in the names of Ignatious *et al.* in view of U.S. Patent 5,612,052 issued to Shalaby *et al.* and U.S. Patent 5,366,756 issued to Chesterfield *et al.* and in further view of international Patent Publication WO 92/11844 in the names of Auer *et al.* and U.S. Patent 5,795,922 issued to Demian *et al.* Applicant contends that based on the above-argument that said rejection is erroneous and/or has been overcome by amendment. Applicant respectfully requests the withdrawal of same.

CONCLUSION

Applicant submits that the grounds for rejection asserted by the Examiner have been overcome, and that the claims, as now pending, define subject matter that is novel and nonobvious over the prior art. On this basis, it is submitted that allowance of the instant application is proper, and early favorable action is solicited.

Pursuant to 37 C.F.R. 1.136, Applicant hereby petitions that the period for response to the pending office action be extended for three months to and including June 28, 2005.

Applicant : Shalaby, Shalaby W.
Serial No. : 09/600,648
Filed : October 17, 2000
Page : 22

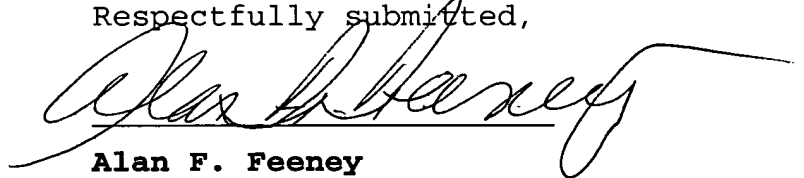
The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Should Examiner Naff deem any further action is required of the Applicants to place this application in a condition for issue, she is requested to telephone the Applicant's undersigned representative.

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Respectfully submitted,



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